PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference HYDRA	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US04/31699	International filing date *(day/month/year)* 27 September 2004 (27.09.2004)	Priority date *(day/month/year)* 29 September 2003 (29.09.2003)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61N 5/10; G21K 5/00; A61B 5/05 and US Cl.: 378/64, 65, 119, 122, 137, 138, 145, 146; 250/423P, 492.1, 492.24, 492.3, 503.1, 505.1; 600/410		
Applicant REIFFEL, LEONARD		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
29 April 2005 (29.04.2005)	24 January 2006 (24.01.2006)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Rhonda for Beel Allen C. Ho Telephone No. (571) 272-1550

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US04/31699

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed.

☒ the description:
pages 1-4 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the claims:
pages 5-8, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the drawings:
pages 1, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☐ the claims, Nos. NONE

☐ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*
*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US04/31699

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 19 and 20	YES
	Claims 1-18	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1-20	NO
Industrial Applicability (IA)	Claims 1-20	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS
Please See Continuation Sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 16 is objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: line 2, "inserted" should be deleted.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 19 and 20 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 19 and 20 are indefinite for the following reason(s): Claim 19 recites "the magnetic field having been changed to be substantially the same in the second slice during the second exposure as in the first slice during the first exposure". It is unclear whether the magnetic field has changed from the first slice to the second slice.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

V. 2. Citations and Explanations:

Claims 1-13 lack novelty under PCT Article 33(2) as being anticipated by Damadian *et al.* (U. S. Patent No. 6,023,165).

With regard to claims 1-9, Damadian *et al.* disclosed a product comprising: a first magnetic field source (**11, 116**) and a second magnetic field source (**12, 117**), which generate a magnetic field of at least one hundred gauss (Column 7, lines 38-54). Note: While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. The only structural elements claimed in claims 1-9 are a first magnetic field source and a second magnetic field source. Magnetic fields and a target volume in a body do not qualify as structural elements.

With regard to claims 10, 12, and 13, Damadian *et al.* disclosed the product of claim 9, wherein at least one magnetic field source from the plurality of magnetic field sources is a superconducting electromagnet (column 5, lines 56-65).

With regard to claim 11, Damadian *et al.* disclosed a product of claim 9, wherein at least one magnetic field source form the plurality of magnetic field sources has power and cooling needs attached via a flexible conduit (column 5, lines 26-55).

Claims 1-10 and 12-18 lack novelty under PCT Article 33(2) as being anticipated by Reiffel (U. S. Patent No. 5,974,112).

With regard to claims 1-9 and 12, Reiffel disclosed a product comprising a first magnetic field source and a second magnetic field source, which generate a magnetic field of at least one hundred gauss (an array of electromagnets, column 5, line 48 - column 6, lines 9). Note: While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. The only structural elements claimed in claims 1-6 is a magnetic field source. Magnetic fields and a target volume in a body do not qualify as structural elements.

With regard to claims 10 and 12, Reiffel disclosed the product of claim 9, wherein at least one magnetic field source from the plurality of magnetic field sources is a superconducting electromagnet (column 5, lines 48-65).

With regard to claim 13, this claim fails to set forth additional structural limitation. Accordingly, it is rejected with claim 9.

With regard to claim 14, Reiffel disclosed a method of tailoring energy deposition, the method comprising: providing a target volume having a target density; providing a body (**23**) having a body density proximal the target volume, wherein the target volume is in the body; providing a magnetic field (**11**); tailoring the magnetic field in a relationship with the body, the target volume, and a electron-photon cascade in the body produced by a photon beam (**21**), where the photon beam and the electron-photon cascade are substantially parallel to a beam path (column 3, lines 44 - 48), wherein the magnetic field has a component (**102**) non-parallel to the beam path in the target volume, which is at least one hundred gauss (column 5, line 48 - column 6, lines 9); and the tailoring relationship causing a desired distribution of energy deposited in the body and the target volume.

With regard to claim 15, Reiffel disclosed the method of claim 14, wherein the magnetic field has a component (**102**) orthogonal to the beam path in the target volume.

With regard to claims 16-18, Reiffel disclosed the method of claim 14, further comprising inserting a magnetic field source in a cavity in the body to produce the magnetic field (column 6, lines 57-59).

Claim 11 lacks an inventive step under PCT Article 33(3) as being obvious over Reiffel (U. S. Patent No. 5,974,112).

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Reiffel disclosed the product of claim 9. However, Reiffel failed to disclose a flexible conduit to provide power and cooling needs to at least one magnetic field source from the plurality of magnetic field sources.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide a flexible conduit to provide power and cooling needs to at least one magnetic field source from the plurality of magnetic field sources, since a person would be motivated to provide a coolant (to lower the superconducting magnet to 2.2 degree K) and power to a superconducting electromagnet.

Claims 19 and 20 lack an inventive step under PCT Article 33(3) as being obvious over Reiffel (U. S. Patent No. 5,974,112).

Reiffel disclosed the method of claim 14. However, Reiffel failed to disclose the method steps of sizing a first exposure of the photon beam so that it irradiates a first slice of the target volume parallel to the photon beam, and sizing a second exposure of the photon beam so that it irradiates a second slice of the target volume parallel to the photon beam, the magnetic field having been maintained substantially the same in the second slice during the second exposure as in the first slice during the first exposure.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to repeat the exposure, since a person would be motivated to repeat the exposure when the target volume is greater than the size of the photon beam.